REMARKS

In an Office Action mailed on March 29, 2005, claims 2, 3, 8, 10-13 and 18-21 were rejected. Claims 2, 3, 10, 12, 13, and 18 have been amended.

Claim objections

The Examiner has objected to claims 2, 3, 8, 10-13 and 18-21 as containing non-elected subject matter. Applicants respectfully request that the objection be withdrawn as claim 2, 3, 10, 12, and 18 have been amended to remove the non-elected subject matter which similarly removes the non-elected subject mater from claims 8, 13 and 19-21 which depend therefrom.

Specification

The Examiner has objected to the specification as the status of prior application 09/302,626 needs to be updated and that the Brief Description of the Drawings needs to be updated for Figure 8. Applicants respectfully request that the objections be withdrawn as the specification has been amended accordingly.

Claim rejection – 35 U.S.C. § 112, second paragraph

The Examiner has rejected claim 13 under 35 U.S.C. § 112, second paragraph, as allegedly being vague and indefinite because it is unclear what is encompassed by "high stringency conditions."

Applicants respectfully disagree. The reaction conditions are not critical to one of skill in the art understanding the metes and bounds of the claim. One of skill in the art is capable of understanding what is encompassed by "high stringency conditions." While there are many different conditions that vary the concentration of salt, temperature, organic solvents and detergents, the basic range of what sequences will and will not hybridize under "high stringency conditions" does not change with differing "high stringency conditions" so much that one of skill in the art would be unable to ascertain the metes and bounds of the patent claims. However, in

order to facilitate prosecution in this case applicants have amended the pending claims, without prejudice or disclaimer, to include wash conditions as requested by the Examiner.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claim 13 under 35 U.S.C. § 112, second paragraph.

The Examiner has rejected claims 8, 12 and 18-20 under 35 U.S.C. § 112, second paragraph, as allegedly being unclear for failing to state a utility.

The applicants respectfully disagree with the Examiner's rejection. Applicants are unaware of any requirement that a claim set forth its utility in order to be definite. To be definite, a claim must set forth the metes and bounds of that which is claimed. The presently pending claims are directed to compositions rather than methods, so the use is not part of the metes and bounds of the physical thing claimed. The Examiner has noted one utility of using the claimed nucleic acid molecules to detect *N. meningitidis*. However, the claimed nucleic acids have other uses such as for expression of immunogenic peptides. As a further example, the Examiner recently allowed U.S. Patent No. 6,822,085 with the following independent claim:

1. An isolated polynucleotide selected from the group consisting of
(a) a polynucleotide which is cysD and which codes for a polypeptide which comprises the amino acid sequence of SEQ ID No. 2,
(b) a polynucleotide which is cysN and which codes for a polypeptide which comprises the amino acid sequence of SEQ ID No. 3,
(c) a polynucleotide which is cysK and which codes for a polypeptide which comprises the amino acid sequence of SEQ ID No. 5,
(d) a polynucleotide which is cysE and which codes for a polypeptide which comprises the amino acid sequence of SEQ ID No. 6, and
(e) a polynucleotide which is cysH and which codes for a polypeptide which comprises the amino acid sequence of SEQ ID No. 8.

The independent claim 1 does not state any utility for the polynucleotides. Thus, clearly claims do not need to state a utility to be definite.

Applicants therefore respectfully request that the Examiner withdraw the rejection of Claims 8, 12 and 18-20 under 35 U.S.C. § 112, second paragraph.

Claim rejection – 35 U.S.C. § 112, first paragraph, enablement

The Examiner has rejected claims 8, 12, 13 and 18-21 under 35 U.S.C. § 112, first paragraph, as allegedly not providing reasonable enablement for isolated nucleic acid sequences which have 50% or greater identity to an isolated nucleic acid sequence set forth in SEQ ID NO:3, isolated nucleic acid sequences which encode 10-mer fragments or isolated nucleic acid sequences which are 80-95% identical to SEQ ID NO:3 with no stated function.

Applicants respectfully disagree. The Examiner has essentially rejected the claims reasoning that some of the embodiments encompassed by the claims may not be operative. This, however, can not be the basis for rejection. As stated by the court in *In re Sarett*, 140 USPQ 474 (CCPA, 1964):

> "In any event, the mere possibility of inclusion of inoperative substances does not prevent allowance of broad claims. The board has so held in Ex parte Lilienfeld, 44 USPQ 174, Ex parte Pechukas, 94 USPQ 390, and Ex parte Friedman, 136 USPQ 381, all cited by appellant. If they are so broad as to be vulnerable, no one but the patentee will suffer from it.
>
> It is certainly not incumbent on an applicant who has made a broad process invention and supported it by an adequately broad disclosure to demonstrate the operativeness of every substance falling within the scope of the broad claims to which he is entitled. In the instant case the research to do this would quite evidently be endless.
>
> The function of claims is to point out the invention and define the scope of the monopoly, not to exclude substances which are possibly of no use in practicing the invention." 140 USPQ at 486.

In order to satisfy Section 112 regarding enablement, the inventors are not required to disclose and claim only operative embodiments of the invention. Instead, in order to satisfy Section 112 regarding enablement, the specification need only set forth such information as is

sufficient to allow one of ordinary skill in the art to make and use the invention. The test of enablement is whether one of ordinary skill in the art can make and use the invention without undue experimentation. The court in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) provided several factors to consider in evaluating whether the experimentation was undue. The relevant factors to consider include the amount of direction provided by the inventor and the existence of working examples. The applicants' specification meets this test for enablement.

In the present case, the invention of claims 8, 19, 20, 21, and 12 pertain to isolated nucleic acid molecules having 50%, 80%, 90%, and 95%, respectively, or greater sequence identity to a nucleic acid encoding SEQ ID NO:4 or 50% or greater sequence identity to a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:3. In addition, the invention of claim 13 pertains to isolated nucleic acid molecules hybridizing under high stringency conditions to a nucleic acid molecule having 50% or greater identity to SEQ ID NO:4. As noted by the Examiner, one utility of all of these claims is detection of the *N. meningitidis* by hybridization with the claimed nucleic acid molecule. Another utility discussed below regarding claim 18 is encoding an immunogenic peptide for expression purposes. The utility and enabling disclosures discussed below regarding nucleic acid molecules encoding immunogenic peptides applies equally to these claims.

The specification provides direction as to conditions for high stringency hybridization as well as how to optimize, design and use probes on pages 46-50 of the specification. This disclosure provides guidance to one of skill in the art to make nucleic acid molecules meeting the high stringency conditions as well as guidance in using all of the nucleic acid molecules in detecting *N. meningitides* nucleic acids. Also, the applicants provide, on page 51, lines 11-21, methods for comparing sequences and determining if a nucleic acid has 50%, 80%, 90%, or 95% or greater identity as applicable. The applicants also provide, on page 53-56, working examples of designing synthetic oligonucleotides that were used to amplify meningococcus B sequences by PCR. Amplification by PCR is one method of detection. Addition of a TaqMan probe would allow easy adaptation to more sensitive RT-PCR detection methods.

In the present case, the invention of claim 18 pertains to isolated nucleic acid molecules that encode immunogenic fragments of SEQ ID NO:4. In Examples 1, 2, and 3, the applicants teach how to determine whether a purified protein is a useful immunogen, and the results of several proteins are illustrated in Figures 1C, 1D, 2C, 2D, 3C, and 3D. Thus, by following the teachings of the present specification, one of skill in the art could determine whether a fragment of SEQ ID NO:4 was immunogenic and encode such protein in a nucleic acid without undue experimentation.

The Examiner's rejection

The Examiner is using an incorrect standard for enablement citing to Mikayama, *et al.* discussing the relationship between the three dimensional structure or a protein and its importance for biological function. In addition, the Examiner cites to Rudinger, *et al.* for the principle that amino acids owe their significance to their inclusion in a pattern which is directly involved in recognition by, and binding to, the receptor. Neither of these cited references is relevant to the utilities discussed above. For example, the function of amino acids in a protein is not relevant to the utility of using the claimed nucleic acid molecules to detect *N. meningitidis* DNA. Regarding the utility of the nucleic acid molecules to express immunogenic peptides, unfolded peptides have long been known to be immunogenic. For example, the Flag-tag is an 8-mer amino acid sequence that can be added to essentially any protein as a purification tag because the 8-mer amino acid sequence is bound by known monoclonal antibodies. Clearly, the context of the rest of the protein to which this 8-mer is affixed is completely irrelevant because the 8-mer can be attached to essentially any protein and it still is bound by the monoclonal antibodies allowing purification of such protein. Furthermore, even if Rudinger, *et al.* were at all relevant to the example utility under discussion, Rudinger, *et al.* was published in June of 1976. More than thirty years have passed since Rudinger, *et al.* was published during which the state of the art has advanced at an astounding rate. Thus, the Examiner has not cited to any support for the proposition that it would require undue experimentation for one of skill in the art to make and use the invention commensurate with the scope as claimed.

The specification teaches how to make and use the invention in terms commensurate with the scope as claimed. The specification must be taken as complying with the first paragraph of § 112 unless there is a reason to doubt the objective truth of the statements relied upon therein for enabling support (*In re Marzocchi*, 169 USPQ 367 (CCPA 1971)). The Examiner has not provided any reason to doubt that the specification is enabling. The Examiner cites to two references discussed above that do not relate to the presently claimed invention, but has not cited to any other evidence.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 8, 12, 13 and 18-21 under 35 U.S.C. § 112, first paragraph.

Claim rejection – 35 U.S.C. § 102(e)

The Examiner has rejected claims 2, 3, 8, 10-13 and 18-21 under 35 U.S.C. § 102(e), as allegedly being anticipated by Peak, *et al.* (U.S. Patent No. 6,197,312). The Examiner has asserted that Peak, *et al.* has a priority date of December 12, 1997.

Applicants respectfully disagree. MPEP § 2136.03(II)(C)(1) clearly indicated that a U.S. Patent which claims priority to an international application filed before November 29, 2000 has a critical reference date as of the earlier of the date of completion of 35 U.S.C. 371(c)(1), (2) and (4) or the filing date of the later-filed application that claimed the benefit of the international application. A courtesy copy of the first page of the international application PCT/AU98/01031 to which Peak, et al. appear to claim priority is enclosed (there is a discrepancy in international patent application number on the face of Peak, et al. [63] and Col 1, line 3-5). Since the international application PCT/AU98/01031 was filed before November 29, 2000, the critical date for Peak, *et al.* is August 9, 1999 (a courtesy copy of the face of Peak, *et al.* with the filing date highlighted has been provided). Since the priority date of the present application is well before August 9, 1999, Peak, *et al.* does not qualify as 102(e) prior art.

Applicants respectfully request that the Examiner withdraw the rejection of claims 2, 3, 8, 10-13 and 18-21 under 35 U.S.C. § 102(e).

CONCLUSION

In light of the above remarks, Applicant submits that the present application is fully in condition for allowance. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicant invites the Examiner to contact the undersigned.

In addition, please direct all further communications in this application to:

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In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 223002099101. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: September 29, 2005

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(12) **United States Patent**
Peak et al.

(10) **Patent No.: US 6,197,312 B1**
(45) **Date of Patent: Mar. 6, 2001**

(54) **SURFACE ANTIGEN**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/377,155**

(22) Filed: **Aug. 19, 1999**

Related U.S. Application Data

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(52) **U.S. Cl.** **424/250.1**; 424/234.1; 424/185.1; 424/190.1; 530/300; 530/350; 536/23.7; 435/69.1; 435/69.3; 435/71.1

(58) **Field of Search** 424/250.1, 234.1, 424/185.1, 190.1; 530/350, 300; 536/23.7; 435/69.1, 69.3, 71.1

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,702,911	*	10/1987	McMichael	424/92
4,769,240	*	9/1988	Brinton	424/92
5,618,541	*	4/1997	Quentin-Millet et al.	424/250.1

* cited by examiner

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(57) **ABSTRACT**

The invention provides a novel surface polypeptide from *Neisseria meningitidis* as well as nucleic acid and nucleic acid sequence homologues encoding this protein. Pharmaceutical compositions containing the polypeptide and nucleic acids of the invention are also disclosed as well as methods useful in the treatment, prevention and diagnosis of *N. meningitidis* infection.

26 Claims, 15 Drawing Sheets

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(57) Abstract

The invention provides a novel surface polypeptide from *Neisseria meningitidis* as well as nucleic acid and nucleic acid sequence homologues encoding this protein. Pharmaceutical compositions containing the polypeptide and nucleic acids of the invention are also disclosed as well as methods useful in the treatment, prevention and diagnosis of *N. meningitidis* infection.